



PATENT  
Customer No. 32692 (3M)  
Attorney Docket No. 54334US019

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: )  
Zheng Z. WU, et al. ) Group Art Unit: 1616  
Application No.: 10/630,414 ) Examiner: Mina Haghigatian  
Filed: July 30, 2003 ) Conf. No.: 9005  
For: C-21 OH 20-KETOSTEROID )  
SOLUTION AEROSOL )  
PRODUCTS WITH ENHANCED )  
CHEMICAL STABILITY )

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. § 1.97(c)**

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), Applicant brings to the attention of the Examiner the documents on the attached listing. This Information Disclosure Statement is being filed after the events recited in Section 1.97(b) but, to the undersigned's knowledge, before the mailing date of either a Final action, Quayle action, or a Notice of Allowance. Under the provisions of 37 C.F.R. § 1.97(c), this Information Disclosure Statement is accompanied by a fee of \$180.00 as specified by Section 1.17(p).

Copies of the listed foreign and non-patent literature documents are attached.

07/06/2007 JADDO1 00000002 10630414

Copies of the U.S. patents, U.S. patent application publications, co-pending applications, and office actions are not enclosed. Applicant respectfully requests that

the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

With respect to the non-English language documents, Applicant has attached English language Derwent Abstracts.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicant determines that the cited documents do not constitute "prior art" under United States law, Applicant reserves the right to present to the U.S. Patent and Trademark Office the relevant facts and law regarding the appropriate status of such documents.

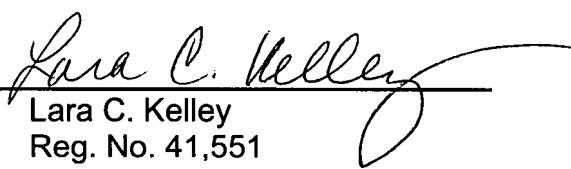
Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: July 5, 2007

By:   
Lara C. Kelley  
Reg. No. 41,551

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

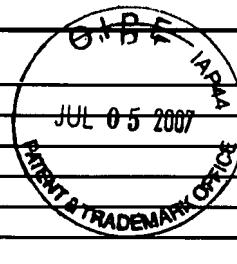
(Use as many sheets as necessary)

Sheet 1 of 5 Attorney Docket Number 03196-0072-01000

**Complete if Known**

Application Number	10/630,414
Filing Date	July 30, 2003
First Named Inventor	Zheng Z. WU, et al.
Art Unit	1616
Examiner Name	Mina Haghigatian

JUL 05 2007


**U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS**

Examiner Initials	Cite No. <sup>1</sup>	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US-3,361,306	01/02/1968	Grim	
		US-3,622,053	11/23/1971	Ryden	
		US-4,185,100	01/22/1980	Rovee et al.	
		US-4,499,108	02/12/1985	Sequeira et al.	
		US-4,579,854	04/01/1986	Iwakuma et al.	
		US-4,835,145	05/30/1989	MacDonald	
		US-5,192,528	03/09/1993	Radhakrishnan et al.	
		US-5,415,853	05/16/1995	Hettche et al.	
		US-5,435,297	07/25/1995	Klein	
		US-5,605,674	02/25/1997	Purewal et al.	
		US-5,642,728	07/01/1997	Andersson et al.	
		US-5,653,961	08/05/1997	McNally et al.	
		US-5,676,930	10/14/1997	Jager et al.	
		US-5,683,677	12/09/1997	Purewal et al.	
		US-5,695,743	12/09/1997	Purewal et al.	
		US-5,891,419	04/06/1999	Cutie et al.	
		US-5,954,047	09/21/1999	Armer et al.	
		US-5,955,058	09/21/1999	Jager et al.	
		US-6,004,537	12/21/1999	Blondino et al.	
		US-6,026,808	02/22/2000	Armer et al.	
		US-6,045,778	04/04/2000	Jager et al.	
		US-6,045,784	04/04/2000	Ruebusch et al.	
		US-6,131,566	10/17/2000	Ashurst	
		US-6,150,418	11/21/2000	Hochrainer et al.	
		US-6,241,969	06/05/2001	Saidi et al.	
		US-6,253,762	07/03/2001	Britto	
		US-6,290,930	08/18/2001	Blondino et al.	
		US-2001/0031244 A1	10/18/2001	Lewis et al.	
		US-6,413,496	07/02/2002	Goodman et al.	

Examiner Signature	Date Considered
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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<i>First Named Inventor</i>	Zheng Z. WU, et al.			
<i>Art Unit</i>	1616			
<i>Examiner Name</i>	Mina Haghigatian			
<i>Attorney Docket Number</i>	03196-0072-01000			

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of

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	US-6,451,285	09/17/2002	Blondino et al.	
	US-2003/0066525 A1	04/10/2003	Lewis et al.	
	US-2003/0077230	04/24/2003	Blondino et al.	
	US-2003/0157028 A1	08/21/2003	Lewis et al.	
	US-2003/0190287 A1	10/09/2003	Lewis et al.	
	US-2003/0190289 A1	10/09/2003	Lewis et al.	
	US-2003/0206870	11/06/2003	Lewis et al.	
	US-6,645,466	11/11/2003	Keller et al.	
	US-2004/0047809 A1	03/11/2004	Lewis et al.	
	US-6,713,047 B1	03/30/2004	Lewis et al.	
	US-2004/0062720 A1	04/01/2004	Lewis et al.	
	US-6,716,414 B2	04/06/2004	Lewis et al.	
	US-2004/0096399 A1	05/20/2004	Lewis et al.	
	US-2004/0184993 A1	09/23/2004	Lewis et al.	
	US-2005/0129621 A1	06/16/2005	Davies et al.	
	US-2005/0142071	06/30/2005	Lewis et al.	
	US-2005/0152846 A1	07/14/2005	Davies et al.	
	US-2005/0154013 A1	07/14/2005	Davies et al.	
	US-2005/0220718 A1	10/06/2005	Lewis et al.	
	US-6,964,759	11/15/2005	Lewis et al.	
	US-7,018,618	03/28/2006	Lewis et al.	
	US-2006/0083693	04/20/2006	Lewis et al.	
	US-2006/120966 A1	06/08/2006	Church et al.	
	US-2005/0165603 A1	07/27/2006	Meakin et al.	
	US-2006/0257324 A1	11/16/2006	Lewis et al.	
	US-7,223,381 B2	05/29/2007	Lewis et al.	

**Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.**

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				<b>Examiner Name</b> Mina Haghigatian
				<b>Attorney Docket Number</b> 03196-0072-01000

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation <sup>6</sup>
		GB 1 525 181	09/20/1978	Syntex Inc.		
		EP 0 372 777 A2	06/13/1990	Purewal et al.		
		WO 91/11173	08/08/1991	Steele et al.		
		WO 92/11236	07/09/1992	Milosovich et al.		
		EP 0 504 112 A2	09/16/1992	Herzog et al.		Abstract
		WO 92/20391	11/26/1992	Adjei et al.		
		WO 93/05765	04/01/1993	Mistry et al.		
		WO 93/11743	06/24/1993	Akehurst et al.		
		WO 93/11747	06/24/1993	Schultz et al.		
		WO 93/18746	09/30/1993	Hettche et al.		Abstract
		WO 94/13262	06/23/1994	Jager et al.		
		WO 94/14490	07/07/1994	Hugemann et al.		
		WO 94/21228	09/29/1994	Duan et al.		
		WO 94/21229	09/29/1994	Duan et al.		
		EP 0 653 204 A2	05/17/1995	Purewal et al.		
		WO 95/17195	06/29/1995	Tzou et al.		
		WO 96/18384	06/20/1996	Sapsford		
		WO 96/19198	06/27/1996	Bäckström		
		WO 96/19968	07/04/1996	Green		
		WO 96/19969	07/04/1996	Otterbeck et al.		Abstract
		WO 96/32150	10/17/1996	Ashurst et al.		
		WO 97/47286	12/18/1997	Oliver et al.		
		WO 98/01147	01/15/1998	Bell		
		WO 98/03533	01/29/1998	Arrow et al.		
		WO 98/05302	02/12/1998	Miller et al.		
		FR 2 756 502	06/05/1998	De LaForcade		Abstract
		WO 98/34595	08/13/1998	Keller et al.		

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				<i>Attorney Docket Number</i> 03196-0072-01000

		WO 98/34596	08/13/1998	Stefely, et al.		
		WO 98/56349	12/17/1998	Lewis et al.		
		GB 2 326 334 A	12/23/1998	Ventura et al.		
		WO 99/12596	03/18/1999	Chiesi et al.		
		EP 0 911 048 A2	04/28/1999	Armer et al.		
		WO 99/64014	12/16/1999	Ekström		
		WO 96/65460	12/23/1999	Blondino et al.		
		WO 99/65464	12/23/1999	McNamara et al.		
		WO 00/06121	02/10/2000	Keller et al.		Abstract
		WO 00/07567	02/17/2000	Keller et al.		Abstract
		WO 00/23065	04/27/2000	Hochrainer et al.		Abstract
		WO 00/35458	06/22/2000	Blondino et al.		
		WO 00/53157	09/14/2000	Musa et al.		
		WO 00/78286 A1	12/28/2000	Wu et al.		
		WO 01/47493 A1	07/05/2001	Cripps, et al.		

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				<i>Examiner Name</i> Mina Haghigatian
				<i>Attorney Docket Number</i> 03196-0072-01000

**NONPATENT LITERATURE DOCUMENTS**

Examiner Initials <sup>a</sup>	Cite No. <sup>b</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation <sup>c</sup>
		Tsi-Zong Tzou et al., "Drug Form Selection in Albuterol-Containing Metered-Dose Inhaler Formulations and Its Impact on Chemical and Physical Stability", Journal of Pharmaceutical Sciences, 1997, Vol. 86, No. 12, pp. 1352-1357	
		S.S. Davis, "Physico-Chemical Studies on Aerosol Solutions For Drug Delivery I. Water-Propylene Glycol Systems", International Journal of Pharmaceutics, 1, 1978, pp. 71-83	
		R.O. Williams, III, et al., European Journal of Pharmaceutics and Biopharmaceutics, Vol. 44, pp. 195-203 (1997)	
		Paul A. Sanders, Ph.D., "Homogeneous Systems and Their Properties", Handbook of Aerosol Technology, Second Edition, Van Nostrand Reinhold Company, NY, pg. 30, 1979	
		P. Hoet et al, "Epidemic of liver Disease Caused by Hydrochlorofluorocarbons Used as Ozone-Spring Substitutes of Chlorofluorocarbons", The Lancet, 1997, Vol. 350, pp. 556-559	
		M.J. Kontny et al, "Issues Surrounding MDI Formulation Development with Non-CFC Propellants", Journal of Aerosol Medicine, 1991, Vol. 4, No. 3, pp. 181-187	
		L.I. Harrison et al, "Pharmacokinetics and Dose Proportionality of Beclomethasone From Three Strengths of A CFC-Free Beclomethasone Dipropionate Metered-Dose Inhaler", Biopharmaceutics & Drug Disposition, 1997, Vol. 18, No. 7, pp. 635-643	
		L. Harrison et al, "Twenty-eight Double-blind Safety Study of an HFA-134a Inhalation Aerosol System in healthy Subjects", J. Pharm. Pharmacol., 1996, Vol. 48, pp. 596-600	
		J. Daly, Jr., "Properties and Toxicology of CFC Alternatives", Aerosol Age, February 1990, pp. 26-27, 40, 56 and 57	
		I.P. Tansey, "Changing to CFC-Free Inhalers: The Technical and Clinical Challenges", The Pharmaceutical Journal, 1997, Vol. 259, pp. 896-898	
		Handbook of Pharmaceutical Excipients, 3rd Ed., (2000) Kibbe Editor, PP. 7-9, 220-222, 234-235 and 560-561	
		G. Brambilla et al, "Modulation of Aerosol Clouds Produced by HFA Solution Inhalers", Portable Inhalers, pp. 155-159, (November 26 & 27, 1998)	
		D. Tiwari et al., "Compatibility Evaluation of Metered-Dose Inhaler Valve Elastomers with Tetrafluoroethane (P134a), a Non-CFC Propellant, Drug Development and Industrial Pharmacy, 1998, Vol. 24, No. 4, pp. 345-352	
		D. Strobach, "Alternatives to CFCs" Part III, Aerosol Age, July 1988, pp. 32-33, 42 and 43	
		Chet Leach, "Enhanced Drug Delivery Through Reformulating MDIs with HFA Propellants-Drug Deposition and Its Effect on Preclinical and Clinical Programs", Respiratory Drug Delivery V, 1996, pp. 133-144	
		B. Meakin, "Fine Particle Dose Control of Solution Based pMDIs", Drug Delivery to the Lungs IX, The Aerosol Society, pp. 1-20, (December 14 & 15, 1998)	
		ABPI Compendium of Data Sheets and Summaries of Product Characteristics, Datapharm Publications Limited, London, pp. 81-82, (1996-1997)	

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